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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/529,125

**Applicant(s)**

LOSHAKOVE ET AL.

**Examiner**

JENNIFER L. HORNBERGER

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
- Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Claim Objections***

1. Claims 10-12 objected to because of the following informalities: Claims 10-12 recite a first leg and second leg, rather than the previous terminology of rail leg and sliding leg. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:  

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
3. Claims 25 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 25 and 28 recite "said tip" in line 2 of each claim. It is unclear whether applicant is referring to the first tip or the second tip.

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:  

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
5. Claims 1, 2, 9, 13, 16-18, 22, 25, 26, and 29-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Kruchinin et al. (WO/9526170).

Regarding claim 1, Kruchinin et al. disclose a sliding surgical clip adapted to connect blood vessel tissue, comprising: an elongate rail leg (1) (Fig. 12) having a main axis and terminating with a first tissue penetrating tip (12); and a sliding leg (6) terminating with a second tip and configured to slide along said rail leg towards said first

tissue penetrating tip, such that said two tips face each other and engage vascular tissue between them (Fig. 13).

Regarding claim 2, Kruchinin et al. disclose the second tip comprises a tissue penetrating tip (12).

Regarding claim 9, Kruchinin et al. disclose the first tip is forked (Fig. 12).

Regarding claim 13, Kruchinin et al. disclose the clip is adapted for use with a blood vessel having a diameter between 2 mm and 40 mm.

Regarding claim 16, Kruchinin et al. disclose the second tip is adapted to penetrate vascular tissue without tearing the tissue.

Regarding claim 17, Kruchinin et al. disclose the elongate rail leg comprises a lock which prevents reverse sliding of said leg.

Regarding claim 18, Kruchinin et al. disclose the elongate rail leg comprises multiple lock locations (7, Figs. 11 and 12) which prevent reverse sliding of said sliding leg.

Regarding claim 22, Kruchinin et al. disclose the elongate rail leg comprises a lock which prevents forward sliding of said rail leg after being locked.

Regarding claim 25, Kruchinin et al. disclose the rail leg defines a temporary locking location distanced from said tip configured to hold said sliding leg prior to said sliding.

Regarding claim 26, Kruchinin et al. disclose the sliding leg engages the rail leg from its outside (Fig. 12).

Regarding claim 29, Kruchinin et al. disclose the sliding leg includes a base section (5) coupled to said rail leg (Fig. 12).

Regarding claim 30, Kruchinin et al. disclose the base section (5) defines an aperture, which aperture fits around said rail leg (Fig. 12).

Regarding claim 31, Kruchinin et al. disclose the fit is snug.

Regarding claim 32, Kruchinin et al. disclose the base section (5) lies in a plane, which plane lies parallel to said main axis (Fig. 12).

Regarding claim 33, Kruchinin et al. disclose the base section (5) lies in a plane, which plane lies perpendicular to said main axis (Fig. 12).

Regarding claim 34, Kruchinin et al. disclose the base section (5) is curved and lies on either side the main axis (Fig. 12).

Regarding claim 35, Kruchinin et al. disclose the base section (5) contacts the rail section at least three points, an axially middle one (at the back of base section (5)) of said points being on opposite sides of said main axis than the other two of said points (each of the prongs of the first tip when the base section has been moved to the last locking groove (7)) (Fig. 12).

Regarding claim 36, Kruchinin et al. disclose the rail leg defines an aperture adapted to receive a suture (Figs 1,2).

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kruchinin et al.

Regarding claim 4, Kruchinin et al. disclose that the base section (5) may comprise a plurality of hooks, but fails to disclose that the hook (6) having a forked tip. However, it would have been obvious to one of ordinary skill in the art to have made the second tip forked in view that the first tip may be forked (Fig. 12) or unforked (Fig. 11) and because it would have provided the same advantage of increased resistance to sliding out of the tissue as adding an additional separate hook to base section.

Regarding claims 5-8, Kruchinin et al. disclose the claimed invention except for the lengths of the first and second tips adapted to enter the blood vessel. It would have been an obvious matter of design choice to make the section of the tips entering the tissue the appropriate length since it would depend of the size of the blood vessel and the blood vessel wall and such a modification would have involved a mere change in the size of the component. A change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955).

Regarding claims 10-12, Kruchinin et al. disclose the claimed invention except for the widths and the lengths of the first and second legs. It would have been an obvious matter of design choice to dimension the legs appropriately, since such a modification would have involved a mere change in the size of the component. A change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955).

8. Claims 3 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kruchinin et al. in view of Kenner (US 6,348,064).

Regarding claims 3 and 23, Kruchinin et al. disclose the claimed invention except for a tissue stop on either of the sliding leg or the rail leg. However, Kanner discloses tissue stops for preventing the penetration of the tissue wall by the prongs. Kanner

teaches that for vascular closure applications it may be desirable that the tissue piercing tapered ends not enter the bloodstream, but rather pierce into the tissue and stop short of piercing through the tissue wall. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have to provide tissue stops, as taught by Kenner, on the tissue piercing tips of the sliding and rail legs in the device of Kruchinin et al. to prevent the tips from piercing all the way through the tissue wall.

9. Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kruchinin et al. in view of Bolduc et al. (US 2004/0172050)

Regarding claim 14, Kruchinin et al. disclose the claimed invention except for the clip being provided as a set of connectors arranged in a generally circular array. Bolduc et al. disclose a plurality of clips (192) coupled to a flexible band (194) or "suture" (paragraph 74, Fig. 11A-11B) for the anastomosis of a graft vessel to a target vessel (paragraph 82, Fig. 13A-13C). Therefore, it would have been obvious to provide a set of the clips of Kruchinin et al. in a generally circular array as taught by Bolduc et al. in order to provided a sealed anastomosis site to attach the a blood vessel or vascular graft to another blood vessel.

Regarding claim 15, Kruchinin et al. fail to disclose the set sutured together at their rail sections. Bolduc et al. disclose a plurality of clips (192) coupled to a flexible band (194) or "sutured" (paragraph 74, Fig. 11A-11B) at their "rail sections" for the anastomosis of a graft vessel to a target vessel (paragraph 82, Fig. 13A-13C). Therefore, it would have been obvious to provide a set of the clips of Kruchinin et al. sutured together at their rail sections taught by Bolduc et al. in order to provide a set of clips which is flexible to fit the shape of the anastomosis to enable a completely sealed connection.

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10. Claims 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krunchinin et al. in view of Blatter et al. (US 2002/0058955).

Regarding claims 19 and 20, Krunchinin et al. disclose the claimed invention except the lock comprising a transaxial extension of said elongate rail which is configured to elastically move out of the way when said sliding leg slides toward said first tip. Blatter et al. disclose two anastomosis rings having locking extensions (340) or "transaxial extensions" disposed on the first ring. The locking extensions, which are adjacent to slots in the rail (as required by claim 20), move out of the way when a second ring is slid towards a first ring until the slots (346) are aligned with the extensions, when the extensions then move back through the slots (346) to lock the rings in place (Figures 3B-3C). Therefore, it would have been obvious to one of ordinary skill in the art to substitute the locking mechanism of Krunchinin et al with locking extensions or "transaxial extensions" of the elongate rail as taught by Blatter et al. to achieve the predictable result of the rail leg and sliding leg being locked in place.

Regarding claim 21, Blatter et al. fail to disclose the transaxial extension is robust enough to withstand a force of at least 1 Kg on said extension. It would have been obvious to one having ordinary skill in the art at the time of the invention was made to discover the minimum force for the extension to withstand, since it has been held that discovering the optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Regarding claim 27, see discussion of Blatter et al. and Krunchinin et al for claim 19 above for modification of Krunchinin et al. to disclose a clip wherein the rail leg defines a slot along its length and wherein said sliding leg engages said rail leg from said slot (Fig. 3B-3C).



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11. Claims 24 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kruchinin et al. in view of Bremer et al. (US 6,022,351).

Regarding claim 24, Kruchinin et al. disclose the claimed invention except for the rail leg defines a weakened location adapted to be selectively torn when sufficient force is applied to opposite sides of said weakened location. Bremer et al. disclose a weakened portion to enable breaking off the extra portion of a shank or "rail leg" after a fastener has been tightened. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a weakened location in the rail leg in the device of Kruchinin et al. so that the extra portion of the rail leg could be torn off after tightening of the clamp.

Regarding claim 37, Kruchinin et al. disclose a method of deploying a clip, comprising: engaging vascular tissue using a hooked section of a rail leg; sliding a hooked sliding leg along said rail leg until it engages said tissue; locking said sliding leg to said rail leg. Kruchinin et al. fails to disclose tearing a section of said rail leg off adjacent a locked location of said sliding leg. Bremer et al. disclose a weakened portion to enable breaking off the extra portion of a shank or "rail leg" after a fastener has been tightened. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to tear the extra section of the rail leg off after tightening and locking the device of Kruchinin et al. because it would make the clamp smaller and less obstructive to other surgical procedures in occurring the immediate location and prevent the surrounding tissue from catching on the rail leg.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER L. HORNBERGER whose telephone number is (571)270-3642. The examiner can normally be reached on Monday through Friday from 8am-5pm, Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571)272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kevin T. Truong/  
Primary Examiner, Art Unit 3734

jlh  
3/7/08